CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 31.7
TITLE: LIVER TRANSPLANTATION

AUTHORITY: 38 CFR 17.270(a); 17.272(a)(1)(4)(13)(14)(59) and 17.273

RELATED AUTHORITY: 32 CFR 199.4(e)(5)(v)

I. EFFECTIVE DATES

A. July 1, 1983

B. August 1, 1992, for living-related donor liver transplantation (LRDLT)

C. October 26, 1992, for removal of medical indications list

D. November 1, 1994, for hepatitis C

E. December 1, 1996, for hepatitis B

F. September 1, 2001, for adult hepatocellular carcinoma (under certain circumstances)

II. PROCEDURE CODE(S)

A. CPT codes: 47133-47136, and 47140-47142

B. ICD 9 CM codes: 50.51 and 50.59

III. POLICY

A. Liver and living related donor liver transplantation (LRDLT) require pre-authorization.

B. Liver and LRDLT transplantation is covered for beneficiaries when the transplantation is performed at a Medicare-certified, TRICARE-certified, or TRICARE-certified pediatric consortium liver transplantation center for beneficiaries who:

1. are suffering from irreversible hepatic disease (to include hepatitis B or hepatitis C);

2. have exhausted more conservative medical and surgical treatments;

3. are approaching the terminal phase of their illness (e.g., death is imminent, irreversible damage to the central nervous system is inevitable, or the quality of life has deteriorated to unacceptable levels);

4. demonstrated plans for long-term adherence to a disciplined medical regimen are feasible and realistic; and

5. if, suffering from alcoholic cirrhosis, the following criteria should be met:

a. there should be evidence of sufficient social support to assure assistance in alcohol rehabilitation and immunosuppressive therapy following the operation;

b. patient is abstinent (for at least six months prior to the transplantation is recommended), it is the responsibility of the transplant facility to determine if the patient is a transplant candidate;

c. there is no evidence of other major organ debility (e.g., cardiomyopathy); and

d. evidence of ongoing participation in a social support group, like (Alcoholics Anonymous).

C. Hepatitis B and pneumococcal vaccines for patients undergoing transplantation are covered.

D. Hepatocellular carcinoma when the following conditions are met:

1. the patient is not a candidate for subtotal liver resection;

2. the patient's tumor(s) is less than or equal to 5cm in diameter;

3. there is no macrovascular involvement; and

4. there is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone.

E. DNA-HLA tissue typing for determining histocompatibility is covered.

F. Pre-authorized services and supplies related to LRDLT that are medically necessary can be cost shared for:

1. evaluation of a potential candidate's suitability for liver transplantation whether or not the patient is ultimately accepted as a candidate for transplantation;

2. pre- and post transplant inpatient hospital and outpatient services;

3. pre- and post-operative services of the transplant team;

4. the donor acquisition team and all costs of transportation for the team and donor organ to the location of the transplantation center;

5. the maintenance of the donor organ is covered after all existing legal requirements for excision of the donor organ has been met;

6. donor costs;

7. the blood and blood products required for the transplantation;

8. FDA approved immunosuppression drugs, to include off-label uses, when medically necessary;

9. the complications associated with the transplantation procedure, including inpatient care, management of infection and rejection episodes;

10. the periodic evaluation and assessment of the successfully transplant patient; and

11. air ambulance may be cost shared when determined to be medically necessary (see Chapter 2, Section 32.1, *Ambulance Service*).

IV. POLICY CONSIDERATIONS

A. Pre-authorization or retrospective authorization of liver and LRDLT is required. When pre-authorization was not obtained, but patient meets (or as of the date of transplantation, would have met) the patient selection criteria, CHAMPVA benefits may be extended. The claim will be reviewed to determine whether the beneficaries condition meets the clinical criteria for transplantation.

B. The transplant facility is (or as of the date of transplantation, would have been) Medicare-certified, TRICARE-certified, or TRICARE-certified pediatric consortium liver transplantation center.

C. Claims for services and supplies related to the transplantation will be reimbursed based on billed charges.

1. Charges from the donor hospital will be cost shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the CHAMPVA patient (see Chapter 2, Section 31.1, *Donor Costs*).

2. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation may be cost shared.

3. Acquisition and donor costs are not considered components of the services covered under the DRG. These costs must be billed separately on a standard UB-92 claim form in the name of the CHAMPVA patient.

4. When a patient is discharged (less than 24 hours) due to circumstances that prohibit the authorized transplant, such as the available organ is found not suitable, all charges will be cost shared on an in-patient basis. When admitted, the expected stay was for more than 24 hours.

V. EXCEPTIONS

Liver or LRDLT transplantation performed on an emergency basis in an unauthorized liver transplant facility may be cost shared only when the following conditions have been met:

1. the unauthorized center must consult with the nearest Medicare authorized liver transplantation center regarding the transplantation case; and

2. it must be documented by the transplantation team physician(s) at the authorized liver transplantation center that transfer of the patient (to the authorized liver transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

VI. EXCLUSIONS

A. Services/supplies provided at no cost or if the beneficiary (or sponsor) has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center. [38 CFR 17.272(a)(1)]

B. Services/supplies not provided in accordance with the applicable program criteria (i.e., part of a grant or research program, unproven procedure). [38 CFR 17.272(a)(13)]

C. Services, supplies or devices, even those used in lieu of the transplantation, when determined to be related or integral to an experimental or investigational (unproven) procedure, may not be cost shared under CHAMPVA (see Chapter 2, Section 16.5, *Experimental/Investigational (Unproven) Procedures*). [38 CFR 17.272(a)(14)]

D. Pre-or post-transplantation non-medical expenses (i.e., out-of-hospital living expenses, to include hotel, meals, and privately owned vehicle for the beneficiary or family members). [38 CFR 17.272(a)(4)]

E. The transportation of a living organ donor or cadaver. [38 CFR 17.272(a)(59)]

F. Administration of an experimental or investigational (unproven) immunosuppressant drug that is not FDA approved or has not received approval as an appropriate "off label" drug indication (see Chapter 2, Section 30.8, *Immunosupression Therapy*).

G. Liver transplantation and LRDLT is excluded when any of the following contraindications exist:

1. adult transplantation for all malignancies, except for hepatocellular carcinoma, as indicated under policy;

2. significant or advanced cardiac, pulmonary, renal, nervous system or other systemic disease;

3. systemic infection;

4. acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs;

5. active alcohol or drug abuse;

6. the need for prior transplantation of a second organ, such as a lung, heart, kidney or marrow, if this represents the coexistence of significant disease; or

7. the history of a behavior pattern or psychiatric illness that might be considered to interfere significantly with the compliance of a disciplined medical regimen over a long duration.

H. Artificial assist devices. Assist devices are generally used for a bridge to transplantation until a suitable donor becomes available. Assist devices when used as a bridge to transplantation are considered investigational or experimental (unproven). [38 CFR 17.272(a)(14)]

END OF POLICY